

### REMARKS

The foregoing Amendment cancels the claims that corresponded to the count in Interference No. 104789.

Claims 4-6 and 8 have been objected to by the Examiner who stated that they may be allowable if rewritten in independent form. Claim 4 has been rewritten into independent form. All of the other claims now in this application are directly or indirectly dependant from Claim 4.

Claim 10 covered certain subject matter that was not included in the Interference. Newly presented Claim 38 is directed to this subject matter.

Claims 39-41 cover, respectively, the subject matter of former Claims 11, 12 and 15.

#### Claim 4

In objecting to Claims 4-6 and 8, the Examiner alluded to some discrepancies in the definitions of the substituent groups in the structural formula of Claim 4. He suggested that the preamble of Claim 4 be restated as "A reagent comprising a targeting moiety covalently linked to a metal chelator having the formula ...". Applicants are following this suggestion but have also included, in the preamble, the term "via a bivalent linking group". In addition, the structural formula in Claim 4 has been characterized as depicting both the metal chelator and the bivalent linking group.

In a decision of the Board of Patent Appeals and Interferences dated 25 January 2001, (Paper No. 47 in this application), the Board characterized the invention in the following terms:

The claims are directed to reagent compositions comprising a targeting moiety covalently bonded to a metal chelator having a defined structure. The targeting moiety is "any compound that binds to or accumulates at a target site in a mammalian body", such as monoclonal antibodies, peptides, receptor binding molecules, adhesion molecules, enzyme substrates, enzyme inhibitors, carbohydrates and oligonucleotides. The chelator is a monoamine, bisamide, monothiol chelator capable of forming a complex

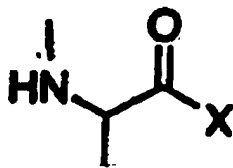
with a radioactive metal, e.g., technetium-99m, through the three N atoms provided by the amine and amide groups of the S atom provided by the thiol group, i.e., an NNNS-type chelator. The claimed reagents are complexed with radioisotopes to provide radiopharmaceutical agents for diagnostic and therapeutic applications.

(Page 2, footnotes and signals omitted). The "covalently bonded" functionality is via the linking group L as defined in Claim 4. There are three distinct functional limitations here: the metal chelator; the bivalent linking moiety; and the targeting moiety. This was recognized by the Administrative Patent Judge in Interference No. 104789 as follows:

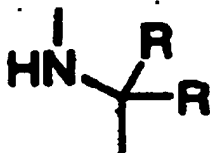
The ordinary meaning of the term bivalent linking moiety is that the moiety functions as a linker between two groups. In the involved claims, the linking moiety "links" a metal chelator to a targeting moiety via a bivalent linkage. The function of the metal chelator moiety is to form two or more bonds to a central metal ion. The function of the targeting moiety is to localize, i.e., bind or accumulate, at a target site.

(Paper No. 95 in Interference 104789, page 17). It is submitted that Claim 4, as well as dependent Claims 5 and 6, now clearly point out the subject matter encompassed in Applicants' claimed reagents.

The Examiner states that "there is no possible substitution on the formula of Claim 2 that would allow for the COX moiety" in Claim 4. The partial structure



in Claim 4 corresponds to the partial structure



of former Claim 2. The group R is defined as "H or R", where R" is substituted or unsubstituted lower alkyl ... not comprising a thiol group". In Claim 4, one R is hydrogen and the other R is R". R" can – according to the specification at page 11, lines 27-29 – be a C<sub>1</sub> alkyl-X where X can be a substituted amine. At page 13, line 16, X is defined as "an amino group, a substituted amino group or –NR<sup>1</sup>-Y, where Y is an amino acid, an amino acid amide, or a peptide comprising from 2 to 10 amino acids". It is recognized that, in Claim 4, the peptide range is from 2 to about 20 amino acids; however, this portion of Claim 4 (as currently amended) was copied from Claim 4 as originally presented and is therefore part of the specification.

#### Claim 8

Claim 8 has been rewritten to depend from Claim 4. In view of the fact that Claim 4 has been rewritten to clearly delineate the three functional groups comprised in Applicants' claimed reagents, it is believed that Claim 8 properly depends from Claim 4.

#### Claim 38

Claim 38 covers the portion of Claim 10 that does not conform to the subject matter of Interference No. 104789.

#### Claims 39-41

Claims 39-41 incorporate the limitations of Claims 11, 12 and 15, respectively. In an earlier stage in the prosecution of this application, these were restricted out and subsequently cancelled. The original requirement for restriction – Paper No. 7 dated 5 December 1995 – was based on seven allegedly distinct inventions. Subsequently, groups I and II were combined; Claims 2-8 and 10 were included in these groups. Since invention III, like the elected claims, covers reagents comprising a targeting moiety, a bivalent linking group and a metal chelator, Applicants believe that invention III is not patentably distinct from the claims that have been examined. Newly-presented Claims 39-41 are all ultimately dependant from Claim 4. It is believed that they are examinable along with the other claims remaining in this application. Applicants are aware of the

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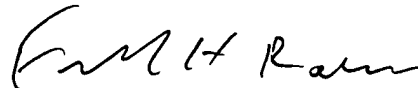
Examiner's stated reasons for maintaining the requirement for restriction of the group III claims – Paper No. 12, dated 13 November 1996. However, Applicants respectfully note that other patents issued to Applicants' assignee have included claims to "reagents" in general and to specific peptides. Enclosed are copies of the cover pages and claims of U.S. Patents Nos. 6,241,965 and 6,358,491.

CONCLUSION

In view of the foregoing Amendment and these remarks, it is believed that all claims in this application are now in condition for allowance. Favorable action is therefore requested.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,



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